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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 11

Application Number: 09/307,633
Filing Date: May 07, 1999
Appellant(s): NIEHOFF, KENNETH J.

Thomas W. Humphrey
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 04 June 2001.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The

Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. In particular, the amendment filed 30 May 2001 concurrently with the brief has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 22, 24, 26, 28 and 30 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,828,547	SAHI et al.	05-1989
5,383,858	REILLY et al.	01-1995

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahi et al.-'547.

Sahi et al. disclose a hypodermic syringe (10) comprising a needle assembly (12) attached to a plunger-type syringe (18). The plunger-type syringe comprises a barrel member (20), analogous to Applicant's claimed body, which is generally hollow and terminates in a nozzle (22) of tapered configuration. A plunger arm (26), analogous to Applicant's claimed extender, terminates in a plunger head (30) at its distal-most end, thereby defining a sealing plunger (24) which is mounted for sliding, reciprocal movement within a main bore (20a) of the barrel member. Indicia (I) may be applied to the barrel member as illustrated in Figure 1 to indicate the volume of liquid contained within the main bore. It is the Examiner's interpretation that the indicia on the syringe barrel is shown as incremental lines/notches which are analogous to those of a ruler, thus each line/notch is representative of a measured displacement of the plunger head and is directly proportional to a dose of medicament contained within the syringe barrel. Therefore, the physical indicia is not only related to the syringe capacity but is also representative of the length of the plunger arm and the relative distance of the plunger head from an end of the syringe barrel.

Claims 22-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Reilly et al.-'858.

Reilly et al. disclose a front-loading medical injector (27) and syringe (22). The syringe comprises an elongated main tubular body or barrel (32), a coaxial discharge injection section (34), a plunger (38) slidably positioned within the tubular body and connectable to an actuating mechanism (40) whose components are analogous to Applicant's claimed injector ram. The syringe may also include a mechanism which provides a visual indication of whether the syringe still includes injection liquid, and may have an injector nozzle of reduced diameter surrounded by a screw-threaded cylindrical attachment portion at its injection end. The syringe body is disclosed as being provided with a variety of indicia, among them are reinforcing ribs (74) which are longitudinally spaced so as to also function as volumetric gradations, an encoding device such as a bar code having spaced bars (70b) or a series of raised surfaces (70s) which are read by a sensor on the injector, and/or an indicating mechanism (76) which detects the presence or absence of a liquid in the syringe via a plurality of integrally molded, textured dots (78). Also disclosed are other mechanically readable devices such as a slot, a hole, or projections which register against a switch on the mounting assembly thereby sending information concerning the type of syringe to the injector system. The encoding device is disclosed as capable of conveying a variety of information to the injector such as the dimension of the syringe, content of the syringe in the case of a pre-filled syringe, manufacturing information such as lot numbers or dates, recommended rates and pressures, and loading/injection sequences. It is the Examiner's interpretation that the reinforcing ribs on the syringe barrel are analogous to those of a ruler, thus each rib is representative of a measured displacement of the plunger head and is directly proportional to a dose of medicament contained within the syringe barrel. Therefore, the physical indicia is not only related to the syringe capacity but is also representative of the length

of the plunger arm and the relative distance of the plunger head from an end of the syringe barrel.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-3 of U.S. Patent No. 5,928,197. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims recite structural elements previously disclosed in the narrower claim language of the above listed patent.

Claims 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,662,612. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims recite structural elements previously disclosed in the narrower claim language of the above listed patent.

As noted in Paper No. 8, Applicant intends to file a terminal disclaimer to overcome the above double-patenting rejection, however as of yet, no terminal disclaimer has been received.

(11) Response to Argument

With response to Applicant's arguments to the applicability of Sahi et al. (US 4,828,547), the Examiner understands that it is Applicant's intention to seek coverage for a physical indicia on a syringe body which is read/detected/sensed by an injector system utilized therewith. Applicant's indicia conveys information related to the syringe to the injector system, for example, the syringe's capacity, the distance traveled by the plunger head within the syringe body, or other related information.

The major point of contention being the term "physical indicia", Applicant seems to be of an opinion which differs from that of the Examiner. The Examiner has taken this term to be representative of an indicating mechanism which is physical, therefore in the case of Sahi et al. (US 4,828,547), the indicia (I) being applied to the surface of the syringe barrel (20) would inherently be physical, as it is found to be applied to the surface of the syringe barrel in the form of grooves/indentations, raised surfaces, sticker/adhesive label, or as being in any other known form. **Sahi et al.'s indicia may not be physically recognizable by an injector system, but that limitation has not been set forth within the claim language.** Additionally, Sahi et al.'s indicia extends along the entire length of the barrel, therefore it is the Examiner's opinion that the gradation nearest the proximal end of the syringe barrel is **related** to the capacity of the syringe. The Examiner does not dispute that Applicant's specification discloses an invention which differs from that which is disclosed by the prior art relied upon above, however the structural difference is not set forth in the claim language.

With regard to Reilly et al. (US 5,383,858), the indicia is disclosed as taking many forms such as reinforcing ribs (74) representative of volumetric gradations, mechanically readable devices in the form of a slot, a hole or projections, an encoding device in the form of a bar code (70b) or raised surfaces (70s) which are read by an injector system used therewith to convey information about the syringe dimensions, content of a pre-filled syringe, etc., and finally an indicating mechanism (76) which detects the presence or absence of a liquid in the syringe via a plurality of integrally molded, textured dots (78). It is the Examiner's opinion that Reilly et al.'s forms of indicia are "physical" because they are all physically present, in the form of annular rings integral with the syringe barrel, as a bar code similar to a UPC symbol, or textural deviations such as molded dots. Thus, the interpretation of the term "physical indicia" is not limited to Applicant's definition, but rather may be construed by one having ordinary skill in the art to be analogous to that which is disclosed in the prior art relied upon. In conclusion, **Reilly et al.'s indicia in at least one form, i.e. mechanically readable devices, are physically recognizable by the injector system, thereby anticipating the claimed limitations of Applicant's invention.**

Finally, the Examiner would like to address, the phraseology "related to", Applicant's representative consistently states that both Sahi et al. (US 4,828,547) and Reilly et al. (US 5,383,858), do not suggest indicia that indicates syringe capacity, or initial position of the plunger, or the end travel or range of travel of a ram of an injector using a syringe. It is the Examiner's opinion that given the "related to" phraseology's use, in independent Claims 22, 24, 26, 28, and 30 when describing the "physical indicia", leaves room for interpretation, and in the broadest sense does not necessitate that the prior art have the exact limitation following said

phraseology. Instead the limitation following said phraseology can be subject to deductive logic, thus *for example* when considering the phrase "physical indicia ....*related to* the capacity of said syringe", the Examiner has concluded that Sahi et al.'s indicia with regard to the syringe barrel's maximum dosage is "related to" and indicative of the syringe's capacity. With reference being made to Reilly et al.'s volumetric gradations the same argument as stated with respect to Sahi et al. applies, alternatively with regard to Reilly et al.'s encoding device it is disclosed that the information contained therein could include dimensions of the syringe, which the Examiner has interpreted as being "related to" the syringe's capacity, as one could easily deduce a syringe's capacity from its dimensions.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

J Maynard
August 13, 2001

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